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# Legislative Notice

Editor, Judy Gorman Prinkey

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## S. 1601 – Human Cloning Prohibition Act of 1998

Calendar No. 304

Introduced on February 3, 1998, by the Majority Leader on behalf of Senators Bond, Frist, Gregg, *et al*, and placed on the Calendar on February 4. An identical bill, S. 1599, was introduced the same day and referred to the Committee on the Judiciary. No report.

### NOTEWORTHY

- No unanimous consent agreement governs the consideration of S. 1601, but the Majority Leader intends to seek consent for its consideration today. It is likely cloture will be filed, in which case a vote on cloture is likely on Tuesday, February 10.
- S. 1601 prohibits human cloning, specifically, the use of somatic cell nuclear transfer technology for the purpose of human cloning. [For details of what this means, see "Background," page 2.] The bill also prohibits the importation of cloned human embryos created by somatic cell nuclear transfer.
- The bill also provides for criminal and civil penalties for violations of the prohibitions of human cloning or importing human clones; establishes a National Commission to Promote a National Dialogue on Bioethics; and protects other areas of genetic research that do not involve human cloning.
- Likely amendments include the substitute text of S. 1602, introduced by Senators Feinstein and Kennedy, which would ban not human cloning but the implantation of a cloned cell into a woman's uterus. [For details of what this means, see "Background."]
- Because the prohibitions in S. 1601 focus narrowly on cloning by somatic cell nuclear transfer, sponsors say they would not interfere with important research such as gene therapy; cloning of DNA, molecules, cells, tissues, plants and animals; stem cell research; and other work. The bill states that nothing in it shall be construed to restrict areas of scientific research that are not specifically prohibited.

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## BACKGROUND

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In February 1997, the media reported that a scientist in Scotland, Dr. Ian Wilmut, had successfully cloned an apparently healthy lamb (named Dolly) from an adult sheep. Dolly, a genetic twin adult, was the only live birth to result out of 277 attempts. Prior to her successful birth, several sheep embryos and fetuses were deformed and/or spontaneously aborted.

Soon after this announcement, President Clinton directed the National Bioethics Advisory Commission (NBAC) — a 15-member commission created by the President under Executive Order 12975 of October 3, 1995, all the members of which are appointed by the President — to examine the “ethical questions” surrounding cloning, “particularly with respect to the possible use of this technology to clone human embryos.” On March 4, 1997, he issued what he described as a moratorium on federal funding of human cloning and asked the private sector to impose a voluntary moratorium on itself pending review of the issue by the NBAC.

### ***Brief Description of Cloning by Somatic Cell Nuclear Transfer***

Up until Dolly, the principal way in which researchers achieved getting a genetically identical twin was to split off a cell from an embryo in the early stages of development. These cells, because they have not become “differentiated” — i.e., they have not yet become certain types of cells (blood cells, skin cells, etc., which normally can produce additional cells only of the same type of tissue) — are “totipotent.” Totipotent cells, like a newly fertilized egg cell (the “zygote”), have the ability to give rise to *unlike* cells and thus to form a new individual (or a part of one, such as an organ).

In humans, totipotent cells each have 46 chromosomes (the parts of the cellular nucleus containing DNA, which determines the individual's genetic characteristics) and can develop as an individual human being. (In humans, all the cells of the body except “germ cells” — i.e., eggs and sperm — have 46 chromosomes; germ cells have only 23. At fertilization, the 23 chromosomes from each parent combine to form a new 46-chromosome individual with genetic characteristics from both.) For some time after fertilization, the zygote remains totipotent, but after the development of specialized tissues, the cells become differentiated; they become a part of the whole organism with a specific function, and all the other functions and mechanisms which might have developed are suppressed. These differentiated cells, as distinguished from totipotent cells, are referred to as “somatic” (which means, of the “body”). This is why a cell or a sample of tissue from an adult human cannot be cloned into a new individual, since the somatic cells can only produce tissue of the same type: skin, muscle, etc.

The breakthrough with Dolly was the removal of the nucleus of an adult somatic cell and its transference to a zygote that had had its nucleus removed and, through electrical means, the fusion of the nucleus into the new cell. The result is a totipotent embryo with the genetic information of the adult from which the somatic cell nucleus was taken. This is known as cloning by somatic cell nuclear transfer.

## ***"Creating a Child"***

The cloning procedure described above poses some danger of damage to the genetic information because in the nucleus of an adult cell the genetic material has aged and the DNA can mutate. Consequently, no one knows the health risks to any child created by cloning. This is the reason that the Clinton-appointed NBAC, in its report of June 7, 1997, (Executive Summary, emphasis added) concluded that "*at this time* it is morally unacceptable for anyone in the public or private sector, whether in research or clinical setting, to attempt to *create a child* using somatic cell nuclear transfer cloning." This conclusion was based on the assessment that "current scientific information is not safe to use on humans *at this point*" and would involve "unacceptable risks to the fetus and/or potential child." As such, the NBAC clearly *left open the possibility of support for human cloning* if and when the technological means for doing so safely were to improve.

Also worth notice is the NBAC's reference to "creat[ing] a child" by "somatic cell nuclear transfer *and* implantation [of the cloned zygote] into a woman's body." The NBAC thus left open the question as to whether the initial somatic cell nuclear transfer itself constitutes "creating a child" or whether it is also necessary to implant the cloned zygote into an environment capable of bringing it to birth (i.e., uterine implantation). On June 9, 1997, President Clinton transmitted to Congress a draft bill based on the NBAC's conclusions which he asked Congress to give "prompt and favorable consideration." The President's draft would make it "unlawful for any person...to perform or use somatic cell nuclear transfer with the intent of introducing the product of that transfer into a woman's womb or in any other way creating a human being." The draft is not clear on what is meant by "or in any other way creating a human being."

There is universal agreement that a human embryo, whether or not it is legally recognized as a legal "person" in the constitutional sense, is a form of human life — i.e., a complete human organism. It is clear that the President's objection is not so much to the process of human cloning and the creation of a new embryo (an individual human organism) as it is to allowing that newly created embryo to be implanted and born alive. (This position is consistent with President Clinton's directive to federal agencies in March 1997, prior to the NBAC report, that "no federal funds shall be used for cloning human beings." That directive also refers to "human embryos created for implantation.")

## ***Key Distinction Between Bond/Frist/Gregg and Feinstein/Kennedy***

This question — whether the primary moral hazard constituted in human cloning is creating them *per se* or letting them mature and be born — is the key distinction between S. 1601 (the Bond/Frist/Gregg bill) and President Clinton's perspective, which is the same as that found in S. 1602 (the Feinstein/Kennedy bill). In its central language, S. 1601 (Section 3) makes it unlawful to "use human somatic cell nuclear transfer technology" or to "import a human embryo produced through somatic cell nuclear transfer technology." In sharp contrast, S. 1602 (Section 4) makes it unlawful to "implant or attempt to implant the products of somatic cell nuclear transfer into a woman's uterus" or to engage in commerce in such "products . . . for the purpose of implanting the product of somatic cell nuclear transfer into a woman's uterus."

Accordingly, sponsors of S. 1601 contend that the Feinstein/Kennedy bill (consistent with the Clinton position), unlike S. 1601, would allow live-cloned human embryos to be churned out in assembly-line fashion, as if they were mere bioindustrial products, to be subject to

whatever experiments suited the ingenuity of researchers, so long as they were destroyed. By contrast, S. 1601 would prohibit the creation of such clones in the first place. To date, there has been no national ethical dialogue or review of the potential for mass production of cloned human embryos for research purposes; the Senate debate on S. 1601 will begin that dialogue.

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## **BILL PROVISIONS**

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### **Section 1. Short Title.**

"This Act may be cited as the 'Human Cloning Prohibition Act of 1998'."

### **Section 2. Finding.**

"Congress finds that in order to prevent the creation of a cloned human individual through somatic cell nuclear transfer technology, it is right and proper to prohibit the creation of cloned human embryos that would never have the opportunity for implantation and that would therefore be created solely for research that would ultimately lead to their destruction."

### **Section 3. Prohibition on Cloning.**

This section

- Prohibits any person or entity, public or private, from using somatic cell nuclear transfer for human cloning purposes;
- Prohibits the importation of cloned human embryos created by somatic cell nuclear transfer, including those intended for creation of a human cloned individual; and
- Establishes criminal penalties for violations of up to 10 years in prison, and up to a \$250,000 fine and civil penalties including forfeiture of any profits derived from this type of cloning.

NOTE: The prohibitions on cloning and the penalties established by S. 1601 are amendments to Title 18 of the United States Code (Crimes and Criminal Procedure). By contrast, S. 1602, the Feinstein/Kennedy bill, which carries only civil penalties, amends the Public Health Service Act under Title 42; the prohibitions established under S. 1602 would remain in force only for 10 years.

### **Section 4. Commission to Promote a National Dialogue on Bioethics.**

This section

- Authorizes funding for the establishment of a National Bioethics Commission, to be appointed by the bipartisan Congressional leadership, which would provide an

independent forum for broad public participation and discourse concerning important bioethical issues including cloning;

- Prohibits the politicization of Bioethics by preventing Members of Congress, and Members of the Executive Branch from serving on the Commission; and
- Requires the Commission to report to Congress on an annual basis.

#### **Section 5. Unrestricted Scientific Research.**

Because the prohibition in section 3 focuses narrowly on cloning by somatic cell nuclear transfer, sponsors contend that it would not interfere with important research such as gene therapy; cloning of DNA, molecules, cells, tissues, plants and animals; stem cell research; and other work. Section 5 states that nothing in the Act shall be construed to restrict areas of scientific research that are not specifically prohibited.

#### **Section 6. Sense of the Congress.**

"It is the sense of the Congress that the Federal Government should advocate for and join an international effort to prohibit the use of somatic cell nuclear transfer technology to produce a human embryo."

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### **ADMINISTRATION POSITION**

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No Statement of Administration policy had been received by press time, but it is understood that S. 1602, the Feinstein/Kennedy bill, is consistent with the Administration's position, and that the Administration would support an amendment substituting the text of that bill for the provisions of S. 1601.

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### **POSSIBLE AMENDMENTS**

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Feinstein/Kennedy. Substitute text.

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